K092098 JAN 22 2010

510(k) Summary
Patient Specific Acetabular Reconstruction Prosthesis

Submitter's Name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-5340
Contact Person:	Megan Bevill
Date Summary Prepared:	January 22, 2010
Trade or Proprietary Device Name:	Patient Specific Acetabular Reconstruction Prosthesis
Common or Usual Name:	Acetabular Shell
Classification Name:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87/LPH

Device Description

The Patient Specific Acetabular Reconstruction Prosthesis is an acetabular shell designed to match the natural geometry of an individual patient. Because each Patient Specific Acetabular Reconstruction Prosthesis component is designed to match a particular patient, taking into account his/her natural anatomy and bone stock, a specific device description is not possible.

Intended Use and Indications

The Patient Specific Acetabular Reconstruction Prosthesis is intended to be used in primary and revision surgeries where the acetabulum has deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed below. The device is for single use and is intended for cementless application.

The Patient Specific Acetabular Reconstruction Prosthesis is indicated as follows: rheumatoid arthritis, avascular necrosis, femoral neck fractures, fracture-dislocation of the hip, and unsuccessful cup arthroplasty, endoprosthesis, femoral osteotomy, or girdlestone resection. Indications also include osteoarthritis, traumatic arthritis, slipped capita epiphysis, fused hip and diastrophic variant.

Substantial Equivalence

The Patient Specific Acetabular Reconstruction Prosthesis is similar to the following commercially available devices regarding design features, overall indications, and materials:

- Contour Acetabular Rings (K962541, K040680)
- R3 Acetabular System (K061253, K070756)
- Reflection Acetabular System (K932755, K990666, K060630)
- Patient Matched Flanged Acetabular Component (K983035, K030861)
- Foundation Porous Acetabular System (K973119)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JAN 22 2010

Smith & Nephew, Inc.
c/o Ms. Megan Bevill
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K092098
Trade/Device Name: Patient Specific Acetabular Reconstruction Prosthesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: January 20, 2010
Received: January 21, 2010

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092098

Device Name: Patient Specific Acetabular Reconstruction Prosthesis

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092098